DEFINITIVE REPAIR OF PULMONARY ATRESIA WITH VENTRICULAR SEPTAL DEFECT USING VALVED CONDUIT FOR LOW BODY WEIGHT INFANT

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Pulmonary atresia with ventricular septal defect is a complex congenital heart defect whose management varies depending on the anatomy of pulmonary circulation and surgeon's preferences. The surgical outcomes of complete repair in small infants and neonates in Vietnam have been seldomly reported. We reported our medium-term results of complete repair of this complex lesion using valved conduit in infants and neonates at our institution. The study included 25 patients with the body weight of less than 5kg who underwent definitive repair using valved conduit between January 2016 and December 2021. The median age at surgery was 66 days (IQR 45 – 116 days), and the mean body weight was 4 kg (3 – 5). Most (96%) attended all follow-up visits, and the average follow-up time was 37.4 months (8.4 – 69.3). There was 1 in-hospital death and 2 late mortalities. The 30-days and 5 years survival rate were 96% and 83%, respectively. One patient required conduit replacement at 3 years post operative because of conduit failure. The proportion of patients with freedom from conduit replacement at 5 years was 95%. Three cases required balloon dilatation of the left pulmonary artery due to stenosis. Freedom from all reinterventions and reoperations at 5 years was 52%. Definitive repair of this type of complex heart defect in small infants can be performed safely and resulted in good surgical outcomes.

Keywords: PA/VSD, valved conduit, Rastelli operation.

I. INTRODUCTION

Pulmonary atresia with ventricular septal defect (PA/VSD) is a complex heart defect which is defined as the association of the luminal discontinuity between the right ventricle and the pulmonary trunk, leading to the absence of the antegrade blood flow from the subpulmonary ventricle to the pulmonary artery and an opening in the interventricular septum.[1] In the past, PA/VSD was classified as the most severe variant of the tetralogy of Fallot spectrum due to similar intracardiac morphology so the term tetralogy of Fallot and pulmonary atresia (TOF/PA) was interchangeably used with PA/VSD.[1] Without surgery, only 8% of TOF/PA patients could survive into first decade of life.[2] The goals of surgery consist of seperating the systemic and pulmonary circulations by closure of the VSD and allowing an unobstructed pulmonary blood flow by creating continuity between right ventricle (RV) and pulmonary artery.[3,4] Timing and strategy of the surgery varies among the treating centers' experience and surgeon's preferences.[1,5] There were reports in the literature of the feasibility of performing total repair of this defect in neonatal with good outcomes.[6,7]

Failure of RV function which could be worsened by the pulmonary insufficiency remains a significant risk of mortality and morbidity after cardiac surgery.[8] Meanwhile the

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valved bovine jugular vein conduit which had competent leaflet function has been shown to be an attractive alternative to pulmonary homograft implantation in the reconstruction of right ventricular outflow tract (RVOT) with comparable medium-term results.[9] At Vietnam National Children's Hospital, since 2016, because of the availability of valved conduits, we've routinely performed the Rastelli operation for total correction of PA/VSD patients. For small infants, especially for neonates, the management of these defects is still challenging, and it required an individualized and multidisciplinary approach. The results are seldomly reported, and the question of the safety and feasibility of repair for small infant remains unestablished. This study aimed to evaluate the surgical results of the definitive repair of PA/VSD using the valved conduit in small infants whose body weight was less than 5 kg at Vietnam National Children's Hospital.

II. SUBJECTS AND METHODS

1. Subjects and methods

This was a retrospective observational study. From January 2016 to December 2021, a total of 25 infants whose body weight at surgery were 5 kg or less were diagnosed with PA/VSD and underwent total correction with the use of a valved conduit. Patients' paper and electrical medical records were retrospectively reviewed, and their last check-up status were updated. The outcomes of interest were the rate of survival, rate of freedom from reoperation, and the safety of the surgery. Pre-operative variables (gender, age, weight, heigh, extracardiac abnormality), perioperative variables (operation times, bypass times, cross-clamped times, associated lesions), and post-operative variables (times of mechanical ventilation, length of ICU stay, length of hospital stay) were also collected.

Data extracted from medical records were stored in REDCap and analyzed using Stata software version 17.0. Results were expressed as percentage, mean ± standard deviations, or median with ranges. Rates of survival and freedom from reoperation or reintervention were analyzed by Kaplan-Meier model.

2. Operative considerations

Surgery was performed via median sternotomy. Aortic and bi-caval cannulation were used for cardiopulmonary bypass. Once the cardiopulmonary bypass was established, every left to right shunt (ductus, Blalock-Taussig shunt, central shunt) was occluded and divided. The pulmonary arteries were freely dissected and patched with fresh autologous pericardium for enlargement. Meanwhile the scrub nurse prepared and rinsed the valved conduit in saline solution. For definitive repair, two types of valved conduit were used. One was a valved bovine jugular vein conduit (Contegra® conduit, Medtronics) (fig 1), and the other was a porcine bioprosthesis valved conduit (Hancock® conduit, Medtronics). The size of the conduit was chosen according to the chest's size of the patient. The conduit was cut near to the sino-tubular junction of the tube then the distal anastomosis between the new bifurcation, and then the conduit was performed by a running suture. The aorta was then cross clamped. The VSD was evaluated and exposed via tricuspid valve or right ventriculotomy. The VSD was then closed using a bovine patch and interrupted pledgetted sutures. After right ventriculotomy, resection of hypertrophied muscles was carried out for RVOT enlargement, appropriate to the size of the conduit. The distal end of the conduit was trimmed and anastomosed to the infundibulum's opening. The heart was inspected for any other lesions (ASD, tricuspid valve regurgitation, etc.), then was deaired and closed. Depending on the patient's hemodynamic status, the chest could be left opened prior to ICU transfer.

3. Ethical review

The study was approved by the Research Institute for Child Heath's Ethical Board of Vietnam National Children's Hospital (Issued date: 01 June 2022 / IRB: VN01037/00011976/FWA00028418). Due to the nature of a retrospective study, the informed consent was taken at time of the most recent visit. Information, images, or video relating to the study's subjects are confidential and used only for scientific purposes.

III. RESULTS

1. Demographics

During the study period, 25 infants underwent definitive repair of PA/VSD at our center. There were 15 males (60%). The median age at admission and at surgery was 23 days (IQR 1 - 71) and 66 days (IQR 45 – 116), respectively. Genetic testing was done in 11 patients (44%). Prenatal diagnosis of the heart defect was done in 6 patients (24%). Six patients (24%) had genetic syndromes or extra-cardiac abnormalities including DiGeorge syndrome, hypospadias, cleft palate, anorectal malformation, and micrognathia. Other characteristics of detailed diagnosis and lesions are reported in table 1.

Table 1. Patient Study Demographics

Characteristics	n / X ± SD	%/ (min – max)
Gender		
Male	15	60
Female	10	40
Mean age at surgery	84 ± 55	(16 – 219)
Mean weight at surgery	4.0 ± 0.6	(3 – 5)
Extra-cardiac abnormality	6	24
PA/VSD/PDA	22	88
None	4	16
PGE1	16	64
PDA stenting	1	4
BT shunt	1	4
PA/VSD/MAPCAs	3	12
None	2	8
Uni + Central shunt	1	4
Z-score RPA before surgery	-0.7 ± 1.1	(-3.2 – 1.6)
Z-score LPA before surgery	-0.4 ± 1.4	(-4.3 – 1.9)
Z-score conduit at surgery	2.2 ± 0.7	(0.2 – 4.4)

Characteristics	n / X ± SD	%/ (min – max)
VSD location		
Perimembraneous	19	76
Muscular outlet	6	24
Right aortic arch	8	32
Left superior vena cava	5	20

2. Surgical characteristics and morbidities

At time of definitive repair, one patient had double aortic arch requiring concomitant division of the small left arch; two patients had unifocalization of major aorto-pulmonary collateral arteries (3 anastomoses); five patients (20%) required tricuspid valve repair; and seven patients (30.5%) required closure of the associated atrial septal defect. Valved bovine jugular vein conduit was used in 24 patients (96%); porcine bioprosthesis valved conduit was used in 1 patient (4%) who had a central shunt as previous palliative surgery. Various sizes of conduits were implanted: 8.5 mm in 1 patient (4%), 9.5mm in 1 patient (4%), 12mm in 17 patients (68%), 14mm in 5 patients (20%), and 16mm in 1 patient (4%). The 8.5mm and 9.5mm conduits were made by tailoring the 12mm and 14mm conduit according to the size of the patient's chest. The mean pressure ratio of RV/LV was 0.52 (0.3 – 0.75). Perioperative results are displayed in table 2.

Table 2. Surgical and ICU course characteristics.

Parameters	n	n / X ± SD	% / (min – max)
Operation times (min)	25	250 ± 46	(180 – 360)
CPB times (min)	25	149 ± 27	(110 – 234)
XAo times (min)	25	75 ± 19	(50 – 122)
ICU stay (day)	24	9 ± 8	(4 – 42)
Mechanical Ventilation (hour)	24	125 ± 110	(37 – 490)
Inotropic support (day)	24	8 ± 4	(4 – 16)
Morbidity	25		
Delayed chest closure		3	12
ECMO		3	12
Pleural effusion		17	68
Arrythmias		13	52
Bleeding		6	24

Parameters	n	n / X ± SD	% / (min – max)
PD		6	24
Neurologic symptoms*		4	16
Surgical site infection		11	44
Sepsis		2	8
ETT culture		2	8
Length of hospital stay (day)	24	56 ± 28	(18 – 126)

CPB: cardiopulmonary bypass, XAo: cross-clamped, ICU: intensive care unit, ECMO: extracorporeal membrane oxygenation, PD: Peritoneal dialysis, ETT: endotracheal tube.

**: seizure or hypertonic clonus. MRI results were all normal.*

After surgery, 3 patients required extracorporeal membrane oxygenation (ECMO) support due to cardiac and respiratory distress. Among these 3 patients, 2 (66%) survived. Another six patients (24%) require unplanned reoperations due to bleeding. Overall, in-hospital mortality occurred in 1 patient (4%). Other adverse events included pleural effusion (17/25, 68%), arrythmias (13/25, 52%) which required temporary pacemaker or anti-arrythmias drug such as lidocaine or cordazone, and surgical site infection (11/25, 44%) which did not progress to mediastinitis or deep sternal wound infection.

3. Survival, reintervention/reoperation and follow-up

Information about reoperation/reintervention and mortality are summarized in tables 3 and 4. There was one case in-hospital death. This patient presented at 1 day of age, born to a mother who delivered by C-section at 37 weeks due to her mother's preeclampsia status. The patient was admitted to our hospital due to cyanosis after birth. Her birth weight was 2 kg, with SpO2 at 50% at the room air at admission. Echography revealed a PA/VSD/PDA. Following PGE1 infusion, the SpO2 increased to 80 – 83% at the room air. Despite the abnormal appearance in clinical examinations which might be due to genetic disorders, the karyotyping and FISH tests showed 46XX and no 22q11 deletion. The patient stayed in the hospital until the total correction was performed at 69 day s of age when she was 3kg. A 12mm conduit was used for the repair, with the pressure ratio of RV/LV of 0.43 at the time of operation. The chest was closed on post operative day 1. On post operative day 13, the patient was placed on ECMO due to ventilation associated pneumonia leading to acute respiratory distress syndrome but expired due to irreversible septic shock and severe lung parenchyma damage.

There were 2 late mortalities. One patient died 21 months after surgery at home due to an unknown etiology. Results of her last follow-up visit at 18 months post-surgery were stable. The patient had an abnormal phenotypic appearance, which was likely due to inherited genetic disorder; however karyotyping showed a normal female karyotype (46 XX), and no other genetic testing was done. The other patient died in provincial hospital 5.6 months after his surgery due to pneumonia leading to respiratory distress. Genetic testing from his recent hospitalization revealed 22q11 deletion (DiGeorge syndrome). His last echocardiography showed a dilated RV, RPA

stenosis (PG max 45mmHg), an enlarged main pulmonary artery which measured at 20mm with a PG max of 8mmHg, and moderate pulmonary insufficiency.

Table 3. Reoperation/reintervention etiologies

Patient no.	Duration	Reoperation/Reintervention
1	8.5 months	RVOT obstruction – not related to the conduit
2	10 months 3 years	Left pulmonary artery balloon dilatation and stenting Homograft replacement
3	14 months	Left pulmonary artery balloon dilatation
4	4 years	Distal anastomosis and left pulmonary artery balloon dilatation

Table 4. Mortality Etiology

Patient no.	Gender	Diagnosis	BW	A	W	Mortality	Cause
1	Female	PA/VSD/PDA	2	69	3	In-hos	VAP, sepsis
2	Female	PA/VSD/PDA	2.7	52	3.4	21 ms	Unknown
3	Male	PA/VSD/PDA	2.3	219	4.2	5.6ms	Pneumonia

BW: birthweight A: age at surgery W: weight at surgery VAP: ventilation associated pneumonia

One patient was lost to follow-up. He had been from the hospital discharged without any post-operative complications. The results of his visit at 3 months after surgery showed no significant hemodynamic or anatomic problems after repair. The patient was lost to follow up because the family could not be contacted.

Among the 21 surviving patients, 16 (76%) had NYHA 1 functional status and 5 (24%) at NYHA 2 functional status. The median weight at follow-up was 11kg (IQR 9.5 – 13.7). Pulmonary insufficiency was echographically determined as trivial in 12 patients (57%), moderate in 5 patients (24%), and severe in 4 patients (19%). Echography also showed three patients (14%) had mild aortic regurgitation. The average conduit size at follow up (15.1 mm (CI 95%: 13.1 – 17.1)) significantly increased compared to the time of surgery (12.3mm (CI 95% 11.6 – 13)) (t = -3.167, p = 0.0022).

The mean follow-up time in our study was 37.4 months (8.4 – 69.3). Early and 5 years survival rate were 96% and 83%, respectively (fig 2). There was 1 conduit replacement at 3 years after surgery due to conduit failure. The rate of freedom from conduit replacement at 5 years was 95%. Three balloon dilatations were required due to left pulmonnary artery's stenosis, and 1 reoperation was required due to residual RVOT obstruction which was not related to conduit placement. The overall rate of reedom from reintervention and reoperation at 5 years for our surgical cohort was 52% (fig 3).

IV. DISCUSSION

Timing and management strategy of PA/VSD varies among institutions.[1,5] At Hanoi Heart Hospital, from January 2005 to October 2016, Nguyen et al published a study of 188 PA/VSD patients with the mean age at surgery was 3.2 years.[10] In that study, 106 patients achieved total

repair with an early mortality of 3.8%.[10] Another study recommended total repair at an age of 6 – 8 months if there is favorable pulmonary artery anatomy.[11] In addition, patients with the least complex form of PA/VSD (confluent well developed, bilateral native pulmonary arteries and a ductal dependent pulmonary circulation) while may present with cyanosis in the neonate period, can be managed initially with a PGE1 infusion or with an aortopulmonary shunt,[12] meanwhile the early and inter-staged mortality with shunt related event remains as high as 30% which was not negligible.[13,14] Excellent outcomes of routine total repair of PA/VSD with favorable pulmonary artery's anatomy in the neonate period have been reported.[6,7] In our cohort, only 2 (8%) patients had previous palliative surgery such as an aorto-pulmonary shunt or unifocalization of major aorto-pulmonary collateral arteries, and 23 (92%) patients (including 6 neonates) underwent primary repair at a mean age less than 3 months. Furthermore, at the ICU, these very young patients needed close and careful monitoring in order to detect and treat any complication that might appear.[14] In our study, n/N (44%) patients developed surgical site infections which were treated with regular dressing in order to prevent deep sternal wound infection or mediastinitis. This might be due to very young infants being more likely to get infection. There was a big number of pleural effusion complications which were managed intensively. The reasons for this could be failure of the right ventricular after cardiopulmonary bypass, ventriculotomy, or hypertrophied muscles resection.[15] Regarding the one in-hospital death and two late deaths, the main etiologies were sepsis and pneumonia. The presence of genetic disorders was unclear but a larger study might be helpful because these genetic or extracardiac abnormalities were significant risk factors for mortality (HR=5.56, 95%CI 1.1% - 28.02%, p=0.038).[12] With an early and 5 years survival rates of 96% and of 83% respectively, the definitive repair of PA/VSD for neonate and small infant could be performed safely at Vietnam National Children's Hospital.

Our institution pursues the strategy of an early primary repair in very young infants because we believe that early total correction can potentially avoid complications due to prolonged hypoxia (desaturation), polycythemia, or shunt-related adverse event etc.[16] Studies have shown the effectiveness of aortopulmonary shunts in developing normal pulmonary artery anatomy as the pulmonary blood pressure (allowing for pulmonary artery growth) was as high as systemic pressure.[13] However we hypothesized that an early primary repair restoring normal pulmonary circulation would allow the pulmonary arteries to grow normally after corrective surgery and reduce the need for palliative surgeries. The restoration of normal physiologic antegrade flow from RV to pulmonary artery with a competent pulmonary valve and the extensive pulmonary reconstruction using the fresh autologus pericardium during the definitive surgery will result in pulmonary artery growth and an acceptable RV/LV pressure ratio. In this study, while the left pulmonary artery stenosis could be effectively treated by transcatheter baloon dilatation as in 3 of our cases, the final echocardiography results showed the pulmonary arteries were appropriate to the body size of patients.

In terms of valved conduit implant for RVOT reconstruction, we used porcine bioprosthesis valved conduit (Hancock®) in only one case due to the patient having had a previous surgery (unifocalization of the major collateral arteries to native pulmonary artery). Otherwise, in all of the remaining patients (24 cases), implant using the

valved bovine jugular vein conduit (Contegra®) is preferred to make the connection from the RV to the pulmonary artery. Contegra conduits have been proven not grown in vivo, so in the future, another more ideal conduit might be developed. In the current surgical landscape, the pediatric cardiac surgeon should know and be prepared to conduct implant using the Contegra conduit.[17] In our experience, we found that this valved conduit was easy to handle, and it provided good hemostasis due to the biological tissue nature of the conduit. At follow-up of our cohort, the conduit's diameter grew over time and became significantly larger than at the time of surgical implantation. By echocardiography, variable pulmonary insufficiency severity was observed to be associated with conduit growth. It has been shown that the RV-PA conduit dilation may be caused by high pulmonary pressure, distal conduit stenosis, or peripheral pulmonary artery stenosis.[18] Evaluation of the valved conduit longevity in this subgroup is ongoing. In our cohort, the rate of freedom from reoperation or reintervention at 5 years was 52%. It is still necessary to conduct lifetime follow-up for these patients because of the risk of repeat intervention in the right ventricular outflow tract.

V. CONCLUSION

Definitive repair of pulmonary atresia with ventricular septal defect using valved conduit for very young infants can be performed safely and resulted in good surgical outcomes. A larger long-term study is needed to further understand conduit longevity and physiology when implanted in the right ventricle to pulmonary artery position as well as to assess the long-term quality of life of these patients.

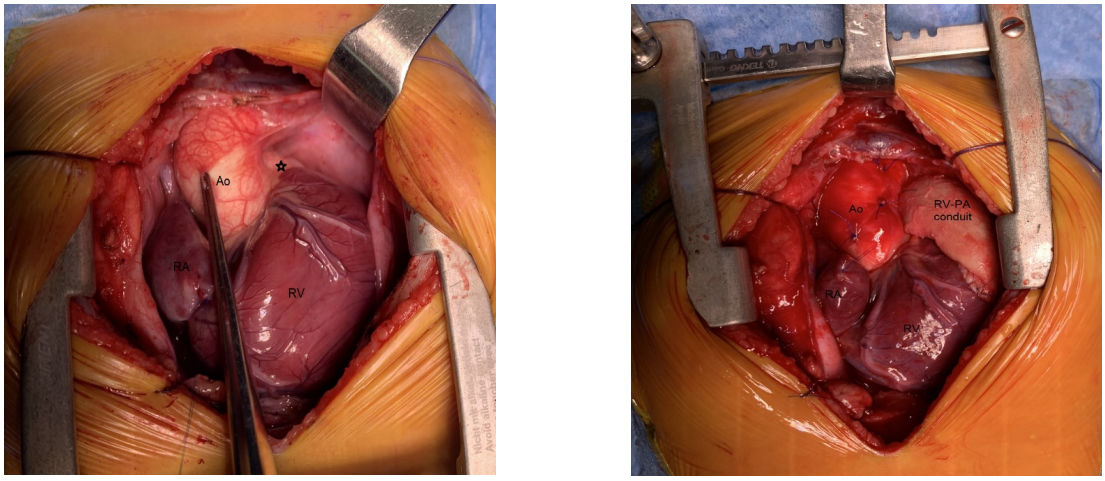

Figure 1. Before and After photos of a 2 months old female, PA/VSD/PDA, 4.2 kg, underwent primary total repair using Contegra valved conduit 12mm. (Ao: Aorta; RA: Right Atrium; RV: Right Ventricle; PA: Pulmonary Artery. ★: Atretic Pulmonary Valve and Hypoplastic pulmonary trunk)

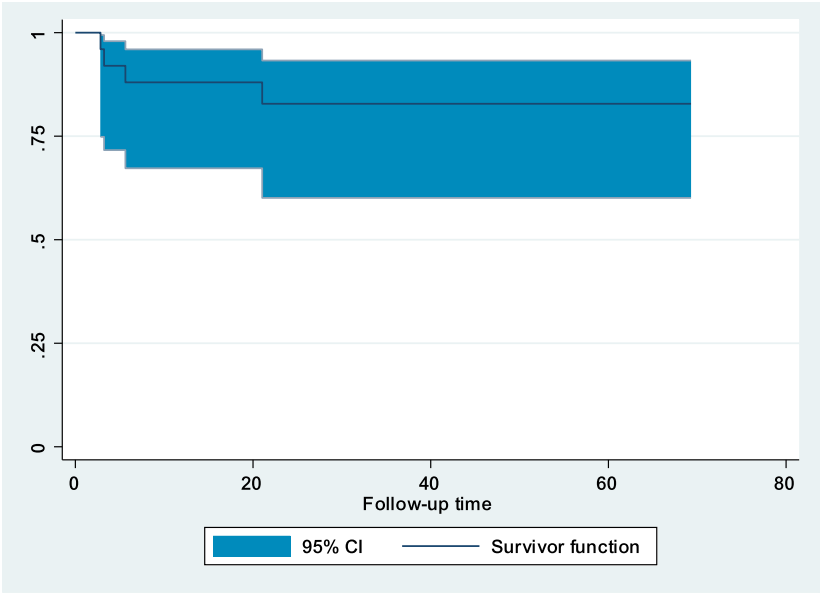

Figure 2. Survival rate estimation during follow-up time

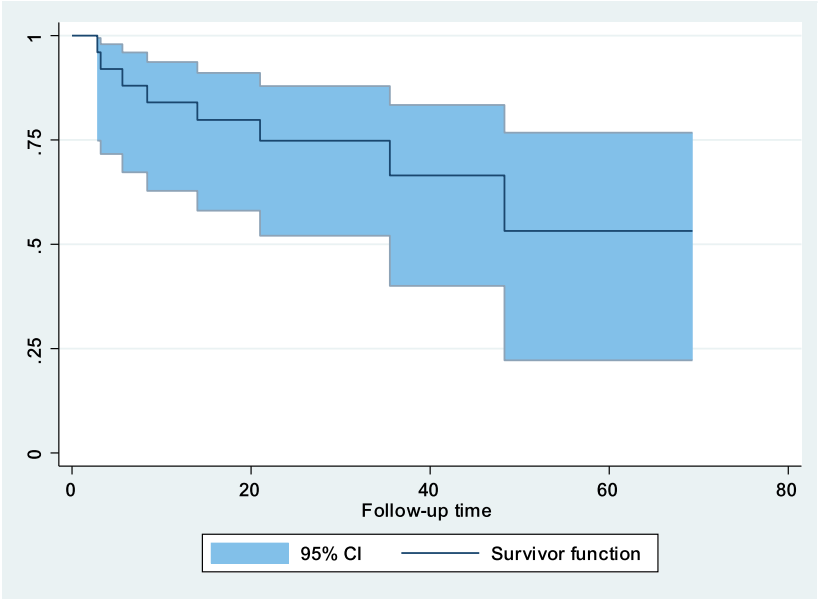

Figure 3. Freedom from reintervention and/or reoperation during follow-up time

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